

Message

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Sent: 3/18/2018 10:25:06 PM
To: Keigwin, Richard [Keigwin.Richard@epa.gov]; Bertrand, Charlotte [Bertrand.Charlotte@epa.gov]; Wise, Louise [Wise.Louise@epa.gov]
CC: Keller, Kaitlin [keller.kaitlin@epa.gov]; Dinkins, Darlene [Dinkins.Darlene@epa.gov]; Layne, Arnold [Layne.Arnold@epa.gov]; McNally, Robert [Mcnally.Robert@epa.gov]
Subject: RE: Update on Science Screen of Oxitec Mosquito EUP

Thanks. I think Kaitlin was finding time for a briefing this week.

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From: Keigwin, Richard
Sent: Sunday, March 18, 2018 8:25 AM
To: Bertrand, Charlotte <Bertrand.Charlotte@epa.gov>; Beck, Nancy <Beck.Nancy@epa.gov>; Wise, Louise <Wise.Louise@epa.gov>
Cc: Keller, Kaitlin <keller.kaitlin@epa.gov>; Dinkins, Darlene <Dinkins.Darlene@epa.gov>; Layne, Arnold <Layne.Arnold@epa.gov>; McNally, Robert <Mcnally.Robert@epa.gov>
Subject: Update on Science Screen of Oxitec Mosquito EUP

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The Biopesticides and Pollution Prevention Division has completed its science screen, mandated by PRIA, of the data submitted in support of the application for an experimental use permit for the Oxitec mosquito. Under PRIA, we have until March 26, 2018, to complete the science screen of the application. Once the registrant is notified of the deficiencies in the application, they will have 10 days to respond. The PRIA due date for a decision on the application is July 25, 2018.

Below is a summary of the deficiencies. I would recommend that BPPD brief the OCSPP IO on the deficiencies before OPP sends the 10-day deficiency letter. OGC has reviewed the deficiencies and is in agreement.

Key Deficiencies Identified in Screen

1. **Ex. 5 - Deliberative Process**

2. **Ex. 5 - Deliberative Process**

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1. Re: tTAV and DsRed2 protein expression levels, the newly submitted whole mosquito expression level study provided additional insight regarding the saliva expression level study that was submitted to both EPA and FDA.

2. Re: DsRed2 allergenicity, the 2017 literature report and updated AllergenOnline database were not available to FDA for their 2016 assessment.

Attached is a one-pager that goes into more detail on the results of the science screen, a draft of the 10-day deficiency letter that we would send to the registrant, and a copy of the article referenced above regarding the potential allergenicity of DsRed2.